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# PATENT COOPERATION TREATY

# PCT



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

2

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| 99 P 2005 P | | |
| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
| PCT/SE00/00572 | 23/03/2000 | 31/03/1999 |
| International Patent Classification (IPC) or national classification and IPC<br>A61N1/365 | | |
| Applicant<br>ST. JUDE MEDICAL AB et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 09/08/2000 | 16.05.2001 |
| Name and mailing address of the international preliminary examining authority:<br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized officer<br>Schoeffmann, H<br>Telephone No. +49 89 2399 2625 |

Form PCT/IPEA/409 (cover sheet) (January 1994)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE00/00572

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
**Description, pages:**

| | | |
|---|---|---|
| 4-6 | as published | |
| 1-3 | with telefax of | 04/04/2001 |

**Claims, No.:**

| | | |
|---|---|---|
| 1-6 | with telefax of | 04/04/2001 |

**Drawings, sheets:**

| | |
|---|---|
| 1/1 | as published |

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 1,2.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1,2 are so unclear that no meaningful opinion could be formed (*specify*):
   **see separate sheet**

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE00/00572

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 3-6 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 3-6 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 3-6 |
| | No: | Claims | |

2. Citations and explanations
**see separate sheet**

**Section III:**

1. Claim 1 relates to a rate adaptive pacemaker having lower rate limiting means preventing the pacing rate from becoming too low. A device according to the preamble of claim 1 is known eg. from US-A-4 535 774 (corresponding to D1 identified below). Claim 1 requires that the lower limit of the pacing rate be adapted such that two criteria concerning cardiac output and stroke volume be met. Since claim 1 however does not specify as to how the lower pacing rate limit should be adapted in dependence of the criteria, a clarity objection arises to claim 1 under Art.6 PCT in that it lacks features essential to the invention.

   Claim 2 does not enlighten the above obscurity so that the same objection arises.

**Section V:**

1. Reference is made to the following documents:

   D1... EP-A-0 140 472
   D3... EP-A-0 576 114

2. The invention pertains to a rate adaptive pacemaker in which the lower pacing rate limit may be adapted so as not become too low. A prescribed suitable lower pacing rate limit may avoid the slow influx of fresh blood. At the same time this lower limit value should be low enough not to disturb a peaceful sleep. The problem is solved by means determining the lower pacing rate limit according to the relations as defined in claim 3 for the case that $SV/SV_{rest} < L$ wherein L lies between 1.2 to 1.5. This solution is not known from the cited prior art, claim 3 therefore meets the requirements of Art.33 (2)-(4) PCT as do claims 4-6 dependent thereon.

   In the rate adaptive pacemaker according to D3 (col.29, line 23 to col.30, line 20) the pacing rate is determined from the difference of long-term and short-term cardiac output. The pacing rate remains however within prescribed upper and lower rate limits (col.30, lines 14-20).

# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

## PCT

### NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|---|---|
| **Date of mailing** (day/month/year)<br>19 December 2000 (19.12.00) | |
| **International application No.**<br>PCT/SE00/00572 | **Applicant's or agent's file reference**<br>99 P 2005 P |
| **International filing date** (day/month/year)<br>23 March 2000 (23.03.00) | **Priority date** (day/month/year)<br>31 March 1999 (31.03.99) |
| **Applicant**<br>MIN, Mart et al | |

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

09 August 2000 (09.08.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

**The International Bureau of WIPO**
**34, chemin des Colombettes**
**1211 Geneva 20, Switzerland**

Facsimile No.: (41-22) 740.14.35

Authorized officer

A. Karkachi

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREA

From the INTERNATIONAL BUREAU

# PCT

## NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

ST. JUDE MEDICAL AB
Patent Department
S-175 84 Järfälla
SUÈDE

**Date of mailing** (day/month/year)
24 November 2000 (24.11.00)

**Applicant's or agent's file reference**
99 P 2005 P

**IMPORTANT NOTIFICATION**

**International application No.**
PCT/SE00/00572

**International filing date** (day/month/year)
23 March 2000 (23.03.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
PACESETTER AB
S-175 84 Järfälla
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address
ST. JUDE MEDICAL AB
S-175 84 Järfälla
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[X] the designated Offices concerned
[ ] the elected Offices concerned
[ ] other:

**The International Bureau of WIPO**
**34, chemin des Colombettes**
**1211 Geneva 20, Switzerland**

Facsimile No.: (41-22) 740.14.35

Authorized officer
C. Cupello

Telephone No.: (41-22) 338.83.38

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00572

## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/365
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | EP 0140472 A1 (MEDTRONIC, INC.), 8 May 1985 (08.05.85), page 11, line 7 - page 13, line 30 | 1-6 |
| A | US 5183040 A (TIBOR A. NAPPHOLZ ET AL), 2 February 1993 (02.02.93), column 19, line 62 - column 20, line 3 | 1-6 |
| A | EP 0576114 A2 (TELECTRONICS N.V.), 29 December 1993 (29.12.93), column 29, line 23 - line 54 | 1-6 |

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 26 June 2000 | 2000 -07- 24 |
| Name and mailing address of the ISA/<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Nikolaj Hautaviita/Els<br>Telephone No. +46 8 782 25 00 |

Form PCT/ISA/210 (second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 00/00572

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| EP 0140472 A1 | 08/05/85 | CA 1243361 A | 18/10/88 |
| | | JP 1701308 C | 14/10/92 |
| | | JP 3068708 B | 29/10/91 |
| | | JP 60034462 A | 22/02/85 |
| | | US 4535774 A | 20/08/85 |
| US 5183040 A | 02/02/93 | NONE | |
| EP 0576114 A2 | 29/12/93 | DE 576114 T | 28/07/94 |
| | | US 5197467 A | 30/03/93 |

09/937875
410 Rec'd PCT/PTO 0 1 OCT 2001
PCT/SE00/00572



# A RATE ADAPTIVE PACEMAKER

## Technical Field

The present invention relates to a rate adaptive pacemaker comprising a means for determining the demand of the patient's organism, a pacing rate controlling means for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low.

## Background Art

The pacing rate of a rate adaptive pacemaker may become too low due to the physical demand of the patient's organism and heart. This may result in lack of oxygen supply to the myocardium. Under certain conditions the heart may not be able to fulfil the physiological needs of the patient's organism and heart if the pacing rate is not limited.

It is previously known to set a lower limit for the pacing rate. This limit value is normally determined from the patient's diagnosis and a constant or externally programmable limit can be set. Thus US-A-4,535,774 describes a stroke volume controlled pacemaker, in which the heart rate is permitted to range between prescribed minimum and maximum heart rate values. Further, in US-A-5,861,011 a pacemaker is disclosed having a system for determining the circadian rhythm by examining variations in the QT interval and adjusting the pacemaker night time setting of a lower rate limit to a lower value than the pacemaker daytime setting of the lower rate limit.

Thus, too low a pacing rate may cause too slow influx of blood enriched with oxygen. A prescribed suitable lower pacing rate limit avoids the slow influx of the fresh blood. At the same time this lower limit value should be low enough not to disturb a peaceful sleep. In that case the patient can feel more healthy in various everyday life conditions including peaceful sleeping.

The purpose of the present invention is to provide a rate adaptive pacemaker in which the pacing rate is prevented in a new way from becoming too low, such that the above discussed inconveniences for the patient are avoided.

Disclosure of the Invention

This purpose is obtained by a rate adaptive pacemaker according to claim 1.

Thus, by satisfying two predetermined relations the pacemaker according to the invention ensures a sufficient minimum energy supply to the patient's organism or body and at the same time the maximum value of the stroke volume is limited and these conditions are continuously automatically checked.

Preferred embodiments are set forth in the dependent claims.

According to an advantageous embodiment of the pacemaker according to the invention the first predetermined relation is

$$CO > CO_{rest} \quad (1)$$

and said second predetermined relation is

$$(SV)/(SV_{rest}) < L \quad (2)$$

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5. In this way the actual cardiac output is ensured not to become lower than the rest state cardiac output $CO_{rest}$ and the actual stroke volume is ensured to be less than a maximum allowed value equal to L x $SV_{rest}$, where L typically has a value between 1.2 and 1.5, depending on the health of the patient's myocardium. By satisfying both these conditions simultaneously a physiologically well founded heart work management at low work loads is ensured.

According to other advantageous embodiments of the pacemaker according to the invention the pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output ($CO_{rest}$) for the patent in rest conditions, and the relation between actual stroke volume (SV) and a rest stroke volume ($SV_{rest}$) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means, and said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke volume SV with stroke volume $SV_{rest}$ for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L \qquad (3)$$

is satisfied and said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV) \qquad (4)$$

where $HR_{rest}$ denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied. In this way the lower pacing rate limit is continuously automatically calculated and it may also happen that the lower pacing rate limit becomes lower than the typical heart rate $HR_{rest}$ for rest conditions of the patient.

According to still another advantageous embodiment of the pacemaker according to the invention a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output CO and actual stroke volume SV from the measured cardiac bioimpedance. In this way these parameters are obtained in an easy and reliable way from the time variation of the bioimpedance measured between a standard intracardiac

*Claims*

1. A rate adaptive pacemaker comprising a means for determining the demand of the patient´s organism, a pacing rate controlling means for controlling the pacing rate in response to the patient´s demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low, **characterized in** that said pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output ($CO_{rest}$) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and rest stroke volume ($SV_{rest}$).

2. The pacemaker according to claim 1, **characterized in** that said first predetermined relation is

$$CO > CO_{rest}$$

and said second predetermined relation is

$$(SV)/(SV_{rest}) < L$$

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5.

3. The pacemaker according to claims 1 or 2, **characterized in** that said pacing rate limiting means includes a lower limit setting means (12) for setting a lower limit value for the pacing rate, and a lower limit determining means (10) for determining the relation between actual cardiac output (CO) and cardiac output ($CO_{rest}$) for the patient in rest conditions and the relation between actual stroke volume (SV) and a rest stroke volume ($SV_{rest}$) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means (12).

4. The pacemaker according to claim 3, **characterized in** that said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke volume SV with stroke volume $SV_{rest}$ for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L$$

is satisfied, and in that said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV)$$

where $HR_{rest}$ denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied.

5. The pacemaker according to any of the claims 2 - 4, **characterized in** that a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output (CO) and actual stroke volume (SV) from the measured cardiac bioimpedance.

6. The pacemaker according to any of the claims 2 - 4, **characterized in** that an ECG measuring and analyzing unit is provided to measure ECG and determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

7. The pacemaker according to any one of claims 1 - 4, **characterized in that** a dynamic distance measuring and analyzing unit is provided to determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

**PCT** WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61N 1/365

A1

(11) International Publication Number: WO 00/57953

(43) International Publication Date: 5 October 2000 (05.10.00)

(21) International Application Number: PCT/SE00/00572

(22) International Filing Date: 23 March 2000 (23.03.00)

(30) Priority Data:
9901194-2 31 March 1999 (31.03.99) SE

(71) Applicant *(for all designated States except US)*: PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE).

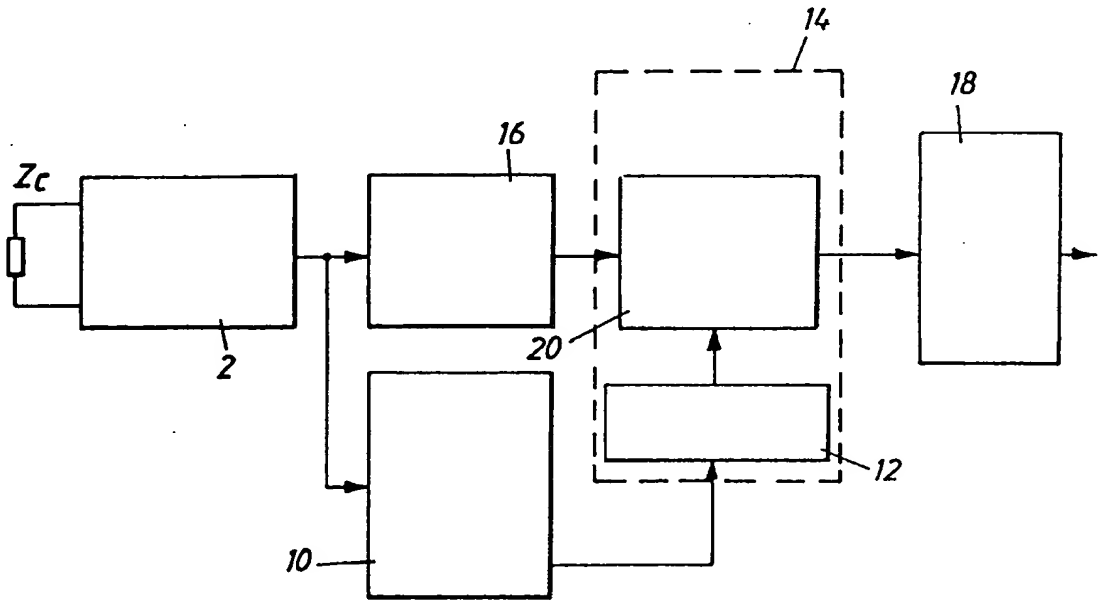
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MIN, Mart [EE/EE]; Söpruse pst. 188A-4, EE-Tallinn (EE). KINK, Andres [EE/EE]; Nabala tee 2A, Kiili, EE-75401 Harjumaa (EE). PARVE, Toomas [EE/EE]; Rännaku blvd. 3-7, EE-10917 Tallinn (EE).

(74) Common Representative: PACESETTER AB; Patent Department, Att: Sven Kalling, S-175 84 Järfälla (SE).

(81) Designated States: US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

**Published**
*With international search report.*
*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: A RATE ADAPTIVE PACEMAKER




(57) Abstract

A rate adaptive pacemaker comprises a means (2) for determining the demand of the patient's organism, a pacing rate controlling means (16) for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means (20) for preventing the pacing rate from becoming too low. The pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output ($CO_{rest}$) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and rest stroke volume ($SV_{rest}$).

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# A RATE ADAPTIVE PACEMAKER

## Technical Field

The present invention relates to a rate adaptive pacemaker comprising a means for determining the demand of the patient's organism, a pacing rate controlling means for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low.

## Background Art

The pacing rate of a rate adaptive pacemaker may become too low due to the physical demand of the patient's organism and heart. This may result in lack of oxygen supply to the myocardium. Under certain conditions the heart may not be able to fulfil the physiological needs of the patient's organism and heart if the pacing rate is not limited.

It is previously known to set a lower limit for the pacing rate. This limit value is normally determined from the patient's diagnosis and a constant or externally programmable limit can be set. Thus US-A-4,535,774 describes a stroke volume controlled pacemaker, in which the heart rate is permitted to range between prescribed minimum and maximum heart rate values. Further, in US-A-5,861,011 a pacemaker is disclosed having a system for determining the circadian rhythm by examining variations in the QT interval and adjusting the pacemaker night time setting of a lower rate limit to a lower value than the pacemaker daytime setting of the lower rate limit.

Thus, too low a pacing rate may cause too slow influx of blood enriched with oxygen. A prescribed suitable lower pacing rate limit avoids the slow influx of the fresh blood. At the same time this lower limit value should be low enough not to disturb a peaceful sleep. In that case the patient can feel more healthy in various everyday life conditions including peaceful sleeping.

The purpose of the present invention is to provide a rate adaptive pacemaker in which the pacing rate is prevented in a new way from becoming too low, such that the above discussed inconveniences for the patient are avoided.

Disclosure of the Invention

This purpose is obtained by a rate adaptive pacemaker according to claim 1.

Thus, by satisfying two predetermined relations the pacemaker according to the invention ensures a sufficient minimum energy supply to the patient's organism or body and at the same time the maximum value of the stroke volume is limited and these conditions are continuously automatically checked.

Preferred embodiments are set forth in the dependent claims.

According to an advantageous embodiment of the pacemaker according to the invention the first predetermined relation is

$$CO > CO_{rest} \quad (1)$$

and said second predetermined relation is

$$(SV)/(SV_{rest}) < L \quad (2)$$

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5. In this way the actual cardiac output is ensured not to become lower than the rest state cardiac output $CO_{rest}$ and the actual stroke volume is ensured to be less than a maximum allowed value equal to L x $SV_{rest}$, where L typically has a value between 1.2 and 1.5, depending on the health of the patient's myocardium. By satisfying both these conditions simultaneously a physiologically well founded heart work management at low work loads is ensured.

According to other advantageous embodiments of the pacemaker according to the invention the pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output ($CO_{rest}$) for the patent in rest conditions, and the relation between actual stroke volume (SV) and a rest stroke volume ($SV_{rest}$) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means, and said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke volume SV with stroke volume $SV_{rest}$ for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L \qquad (3)$$

is satisfied and said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV) \qquad (4)$$

where $HR_{rest}$ denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied. In this way the lower pacing rate limit is continuously automatically calculated and it may also happen that the lower pacing rate limit becomes lower than the typical heart rate $HR_{rest}$ for rest conditions of the patient.

According to still another advantageous embodiment of the pacemaker according to the invention a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output CO and actual stroke volume SV from the measured cardiac bioimpedance. In this way these parameters are obtained in an easy and reliable way from the time variation of the bioimpedance measured between a standard intracardiac

electrode and the housing of the pacemaker, when an excitation current proceeds from the electrode tip.

Brief Description of the Drawings

The invention will now be described more in detail with reference to the enclosed drawings on which figure 1 is a block diagram of an embodiment chosen as an example of the pacemaker according to the invention and figure 2 illustrates the principle of bioimpedance measurements between the tip of an intracardial electrode and the metal housing of the pacemaker.

Description of a Preferred Embodiment

To avoid that the current cardiac output CO

$$CO = SV \times HR \quad (5)$$

becomes lower than the rest state cardiac output $CO_{rest}$ the pacing rate must be above a lower pacing rate limit given by

$$\text{lower pacing rate limit} = (CO_{rest})/(SV) \quad (6)$$

and since

$$CO_{rest} = HR_{rest} \times SV_{rest} \quad (7)$$

$$\text{lower pacing rate limit} = (HR_{rest}) \times (SV_{rest}/SV) \quad (8)$$

In addition thereto the maximum value of the stroke volume must be limited, i.e.

$$SV < L \times SV_{rest} \quad (9)$$

Thus, the following two conditions must be fulfilled simultaneously for insuring a physiologically well founded heart work management at low work loads.

$$\text{Pacing rate limit} > (HR_{rest}) \times (SV_{rest}/SV) \quad (10)$$

$$SV/SV_{rest} < L \quad (11)$$

where L is a constant typically equal to a value of 1.2 to 1.5, depending on the health of the patient's myocardium.

Thus the lower pacing rate limit is continuously automatically calculated from the measured actual stroke volume SV and known values of $SV_{rest}$, $HR_{rest}$ and the constant L. The actual stroke volume can be determined from e.g. bioimpedance measurements as will be described below.

Figure 1 is a block diagram of an embodiment of the pacemaker according to the invention comprising a bioimpedance measurement unit 2 for measuring the time variation of the electric intracardiac bioimpedance $Z_c(t)$. This type of measurements is well known, see e.g. "Design of Cardiac Pacemakers", edited by John G. Webster, IEEE Press, 1995, pp. 380-386 and US-A-5,154,171, 5,280,429, 5,282,840 and 5,807,272. Thus the time variation of the intracardiac bioimpedance can be measured between the tip 4 of the intracardiac electrode 6 and the housing 8 of the pacemaker, when an excitation current is fed from the electrode tip 4, as schematically illustrated in figure 2. Thus a standard pacing lead can be used for this measurement.

From the measured time variations $\Delta Z_c(t)$ the stroke volume SV needed for calculating the lower pacing rate limit according to equation (8) above, or for checking the inequalities (10) or (11), are determined in computing means 10, see figure 1.

The calculated lower limit value is supplied to a lower limit setting means 12 of a pacing rate limiter 14.

A pacing rate controller 16 is also provided for controlling the pacing rate of the pacer or pulse generator 18 in response to the patient's demands. In a limiting unit 20 of the limiter 14 the demanded pacing rate is compared to the set lower limit pacing rate and the actual pacing rate is limited to the set lower limit value if the demanded pacing

rate reaches this limit value. Thus in the pacemaker according to the invention a lower limit value for the pacing rate is continuously automatically determined and it is continuously automatically verified that the actual pacing rate does not exceed the present lower limit value.

Alternatively, the pacemaker can be modified to continuously monitor that the inequalities (10) or (11) above are satisfied.

Above bioimpedance measurements are described for determining the stroke volume SV. This parameter can, however, also be determined by other techniques, like by ECG measurements, by ultrasound technique, by radiometric and optical techniques etc. Generally all dynamic distance and/or capacity measuring methods are applicable.

*Claims*

1. A rate adaptive pacemaker comprising a means for determining the demand of the patient´s organism, a pacing rate controlling means for controlling the pacing rate in response to the patient´s demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low, **characterized in** that said pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output ($CO_{rest}$) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and rest stroke volume ($SV_{rest}$).

2. The pacemaker according to claim 1, **characterized in** that said first predetermined relation is

$$CO > CO_{rest}$$

and said second predetermined relation is

$$(SV)/(SV_{rest}) < L$$

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5.

3. The pacemaker according to claims 1 or 2, **characterized in** that said pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output ($CO_{rest}$) for the patient in rest conditions and the relation between actual stroke volume (SV) and a rest stroke volume ($SV_{rest}$) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means.

4. The pacemaker according to claim 3, **characterized in** that said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke volume SV with stroke volume $SV_{rest}$ for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L$$

is satisfied, and in that said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV)$$

where $HR_{rest}$ denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied.

5. The pacemaker according to any of the claims 2 - 4, **characterized in** that a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output (CO) and actual stroke volume (SV) from the measured cardiac bioimpedance.

6. The pacemaker according to any of the claims 2 - 4, **characterized in** that an ECG measuring and analyzing unit is provided to measure ECG and determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

7. The pacemaker according to any one of claims 1 - 4, **characterized in that** a dynamic distance measuring and analyzing unit is provided to determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

Fig. 1

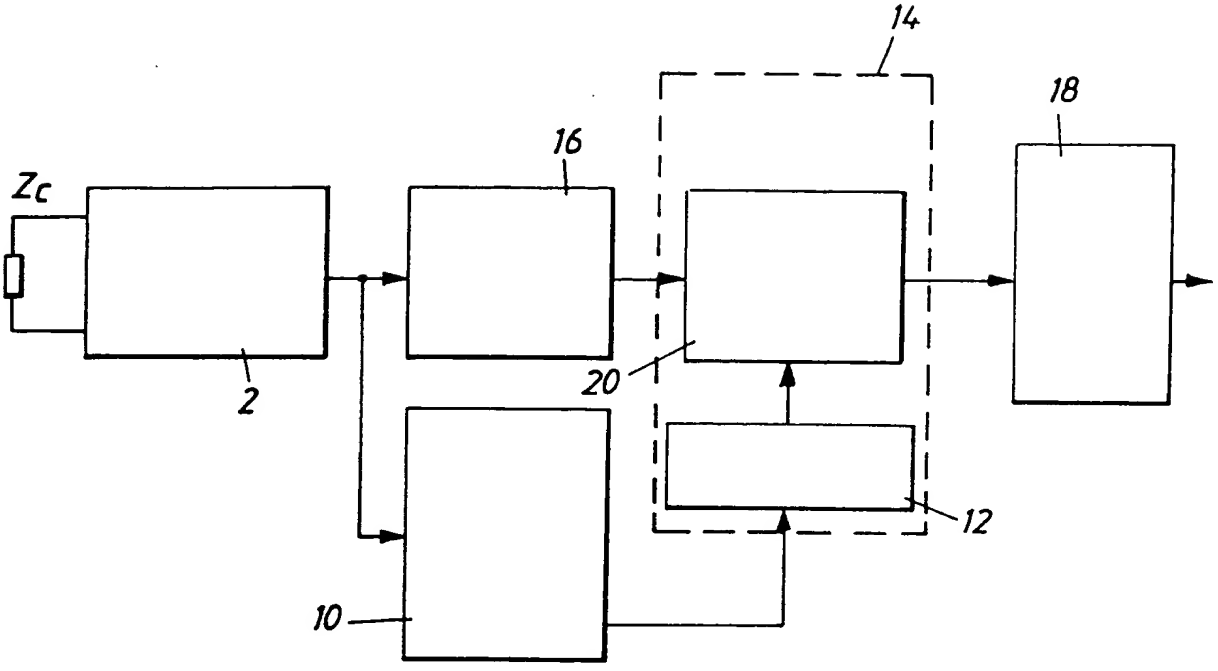
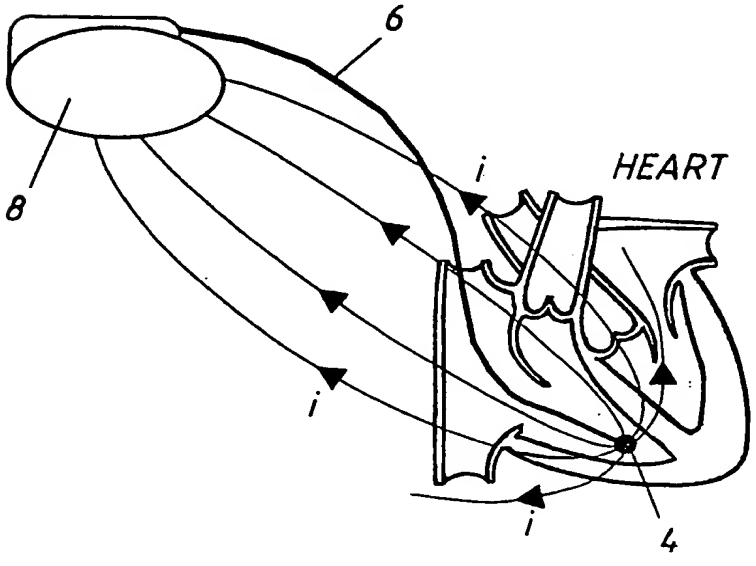



Fig. 2



# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00572

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/365
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | EP 0140472 A1 (MEDTRONIC, INC.), 8 May 1985 (08.05.85), page 11, line 7 - page 13, line 30 -- | 1-6 |
| A | US 5183040 A (TIBOR A. NAPPHOLZ ET AL), 2 February 1993 (02.02.93), column 19, line 62 - column 20, line 3 -- | 1-6 |
| A | EP 0576114 A2 (TELECTRONICS N.V.), 29 December 1993 (29.12.93), column 29, line 23 - line 54 -- -------- | 1-6 |

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 26 June 2000 | 2000 -07- 24 |
| Name and mailing address of the ISA/<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Nikolaj Hautaviita/Els<br>Telephone No. +46 8 782 25 00 |

Form PCT/ISA/210 (second sheet) (July 1992)

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Information on patent family members

02/12/99

International application No.
PCT/SE 00/00572

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